Food and Drug Administration, HHS

§882.4700 Neurosurgical paddie.

- (a) A neurosurgical paddie is a pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.
- (b) Classification. Class II (performance standards).

 $[44~{
m FR}~51730-51778,~{
m Sept.}~4,~1979,~{
m as~amended}$ at 69 FR 10332, Mar. 5, 2004]

§ 882.4725 Radiofrequency lesion probe.

- (a) *Identification*. A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.
- (b) Classification. Class II (performance standards).

§882.4750 Skull punch.

- (a) *Identification*. A skull punch is a device used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.
- (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9. This exemption does not apply to powered compound cranial drills, burrs, trephines, and their accessories classified under §882.4305.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 65 FR 2319, Jan. 14, 2000]

§882.4800 Self-retaining retractor for neurosurgery.

- (a) *Identification*. A self-retaining retractor for neurosurgery is a self-locking device used to hold the edges of a wound open during neurosurgery.
- (b) Classification. Class II (performance standards).

§882.4840 Manual rongeur.

- (a) *Identification*. A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.
- (b) Classification. Class II (performance standards).

§ 882.4845 Powered rongeur.

(a) Identification. A powered rongeur is a powered instrument used for cut-

ting or biting bone during surgery involving the skull or spinal column.

(b) Classification. Class II (performance standards).

§882.4900 Skullplate screwdriver.

- (a) *Identification*. A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patient's skull by screws.
- (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

Subpart F—Neurological Therapeutic Devices

§ 882.5030 Methyl methacrylate for aneurysmorrhaphy.

- (a) Identification. Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or obliteration by aneurysm clip.
- (b) Classification. Class II (performance standards).

\$882.5050 Biofeedback device.

- (a) Identification. A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.
- (b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter when it is a prescription battery powered device that is indicated for relaxation training and muscle reeducation and prescription use, subject to §882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 63 FR 59229, Nov. 3, 1998]